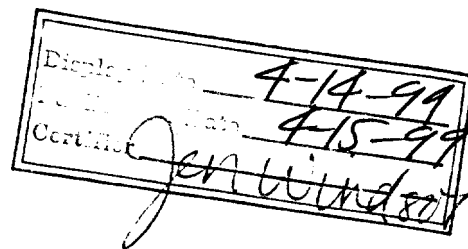


DMB



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

**New Animal Drugs for Use in Animal Feeds; Narasin and Nicarbazine With Bacitracin Methylene Disalicylate and Roxarsone**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for using approved narasin and nicarbazine, bacitracin methylene disalicylate (BMD), and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Alpharma Inc., 'One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-112 that provides for combining approved Maxiban™ (27 grams per pound (g/lb) each of narasin and nicarbazine), BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb BMD), and 3-Nitro® (45.4, 90, or 227 g/lb roxarsone) Type A medicated articles to make Type C medicated broiler chicken feeds. The Type C feed contains 27 to 45 g/ton (t) each of narasin and nicarbazine, 50 g/t BMD, and 22.7 to 45.4 g/t roxarsone. The Type C feed is used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium*

spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

The NADA is approved as of March 4, 1999, and the regulations are amended by adding 21 CFR 558.76(d) (3)(xxi), 558.363(d)(2)(iii), and 558.530(d)(5) (xxv), and by amending 21 CFR 558.366(c) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of Type A medicated articles to make combination drug Type C medicated feeds. Narasin with nicarbazine and roxarsone are Category II drugs as defined in 21 CFR 558.3 (b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make a Type C medicated feed from a Category II drug. Under 21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in NADA 141-112 is limited to manufacture in a licensed feed mill.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11 (e)(2) (ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, room 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

## **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

2. Section 558.76 is amended by adding paragraph (d)(3) (xxi) to read as follows:

**\$558.76 Bacitracin methylene disalicylate.**

\* \* \* \* \*

(d) \* \* \*

(3) \* \* \*

(xxi) Narasin with nicarbazin and roxarsone as in \$558.366.

3. Section 558.363 is amended by adding paragraph (d)(2) (iii) to read as follows:

**§ 558.363 Narasin.**

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(iii) Bacitracin methylene disalicylate, nicarbazin, and roxarsone as in § 558.366.

4. Section 558.366 is amended in the table in paragraph (c) under entry “27 to 45” by alphabetically adding an entry for ‘ ‘Naracin 27 to 45, bacitracin methylene disalicylate 50, and roxarsone 22.7 to 45.4” to read as follows:

**§ 558.366 Nicarbazin.**

\* \* \* \* \*

(c) \* \* \*

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45	Narasin 27 to 45, bacitracin methylene disalicylate 50, and roxarsone 22,7 to 45.4.	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not allow turkeys, horses or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Use as sole source of organic arsenic. Narasin and nicarbazin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573.	046573

5. Section 558.530 is amended by adding paragraph (d)(5) (xxv) to read as follows:

**§ 558.530 Roxarsone.**

\* \* \*

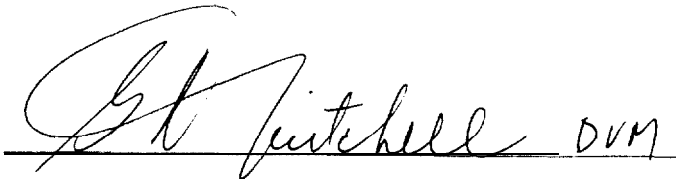
(d) \* \* \*

(5) \* \* \*

(xxv) Bacitracin methylene disalicylate, narasin, and nicarbazin as in \$558.366.

Dated: 4/1/99

April 1, 1999

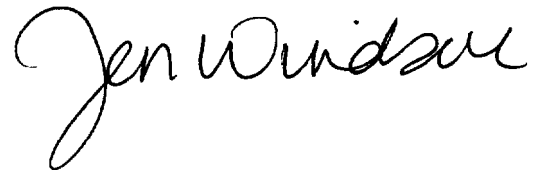
A handwritten signature in cursive script, reading "G A Mitchell", followed by the initials "DVM" in a simpler, blocky script. The signature is written over a horizontal line.

George A. Mitchell  
Acting Director  
Center for Veterinary Medicine

[FR Dec. 99-???? Fified ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

A handwritten signature in cursive script, reading "Jen Windsor".